

510(k) Summary

FEB 14 2014

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

December 24, 2013

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: Shenzhen Beacon Display Technology Co., Ltd
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3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name: 3MP Color LCD Display
Common Name: Display system, medical image workstation, and others
Classification: 892.2050 system, image processing, radiological
Product code: LLZ
Classification Panel: Radiology
Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicates within this submission are as follows:

BARCO N.V., Nio Color 3MP LED has been cleared by FDA through 510(k)
No.K131295 (Decision Date –May 29, 2013),

5. Description of the Device [21 CFR 807.92(a) (4)]

The C32SP+/C32S+ 3MP Color LCD Display is a display system for medical viewing, with high resolution 2048 x 1536, built-in brightness stabilization circuit and ambient light sensor, stable brightness and persistent calibration can be guaranteed. The display can support both landscape and portrait mode. The anti-reflection coated protective screen can prevent display from damage under hard using conditions, make the clean and disinfect easier.

6. Intended Use [21 CFR 807.92(a)(5)]

The C32SP+/C32S+ 3MP Color LCD Display is intended to be used in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Panel	21.3", TFT monochrome LCD screen, antiglare
Brightness (typ.)	1700 cd/m ²
CR (typ.)	1400:1
Viewing angle	R/L 176° , U/D 176° Typ. (CR > 10)
Pixel Pitch	0.2115mm
Native resolution	2048 x 1536
Display area	433.152mm(H) x 324.864mm(V)
Compatible video signals	640 x 480@60Hz(progressive) 2048x1536@60Hz(progressive)
Horizontal resolution	2048 x 1536
Bandwidth	216MHz
Aspect ratio	4:3
Screen size	21.3" real diagonal
Power	DC12V/7.0A
Power consumption	Max. 80 W
Input signals	DVI-D, Display Port
Digital input	TMDS (single)
Plug and play	VESA DDC 2B
Dimension	369.0mm (W) x 482.6mm (H) x 63.6mm (D) (without Stand) 369.0 mm (W) x 626.6 mm (H) x 234.8mm (D) (with Stand)

Weight	6.5kg (without Stand) 9.5kg (with Stand)
Operating temperature and humidity:	Temperature: 0°C ~ 40°C Humidity: 15% ~85%
Storage temperature and humidity:	Temperature: -20°C ~ 60°C Humidity:10% ~90%

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

8.1 Intended uses:

Table 1 Intended Use Comparison

ID	Comparison Item	Proposed Device C32SP+/C32S+	Predicate Device Nio Color 3MP LED
1	Intended Use	The C32SP+/C32S+ 3MP Color LCD Display is intended to be used in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.	" Nio Color 3MP LED" is intended to be used as a tool in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

8.2 Comparison table

Table 2 General Comparison

ID	Comparison Item	Proposed Device C32SP+/C32S+	Predicate Device Nio Color 3MP LED
2	Performance		
2.1	Panel Size and Type	21.3", TFT LCD display	21.3",TFT LCD display
2.2	Pixel Pitch	0.2115 mm	0.2115 mm
2.3	Available Cabinet Colors	Black	Black
2.4	Native Resolutions	2048 x1536	2048 x1536
2.5	Brightness	1700 cd/m2	1700 cd/m2
2.6	Contrast Ratio	1400:1	1300:1
2.7	Network Interface	USB(1 Up, 2 Downstream)	USB(1 Up, 2 Downstream)
2.8	Active Display Size	433.152mm x324.864mm	433.2mm x324.9mm
3	Physical Specifications		
3.1	Dimensions (Wx Hx D)	369.0mm (W) x 482.6mm (H)	375mm x 488mm x 84mm (without Stand)

ID	Comparison Item	Proposed Device C32SP+/C32S+	Predicate Device Nio Color 3MP LED
		x 63.6mm (D) (without Stand) 369.0 mm (W) x 626.6 mm (H) x 234.8mm (D) (with Stand)	Portrait: 375mm x 620~520mm x 235mm Landscape: 488mm x 563~463mm x 250mm (with Stand)
Temperature			
3.2	Operating	0°C ~ 40°C	0°C ~ 40°C
3.3	Transport/ Storage	-20°C ~ 60°C	-20°C ~ 60°C
Relative humidity			
3.4	Operating	15% ~85%	8% ~80%(non-condensing)
3.5	Transport/ Storage	10% ~90%	5% ~95%
4	Power Supply		
4.1	PowerCapacity	<80W	<40W
4.2	Input Voltage	DC12V/7.0A	100~240v
5	Human factors (operation characteristic)		
5.1	Usability	Button operation, LED indicator	Button operation, LED indicator
5.2	Mode of operation	Continuous operation	Continuous operation
6	Biocompatibility		
6.1	Evaluation	The proposed device does not contain any components that come into direct or indirect contact with patients, so the evaluation doesn't be needed.	The proposed device does not contain any components that come into direct or indirect contact with patients, so the evaluation doesn't be needed.
7	Sterility		
7.1	Sterilization	The proposed device does not need sterilization.	The proposed device does not need sterilization.
8	Electrical & Mechanical safety& Thermal safety		
8.1	Type of protection against electric shock	Class I	Class I
8.2	Degree of protection against harmful ingress of liquid	Ordinary equipment.	Ordinary equipment.
8.3	Evaluation	The electrical, mechanical and thermal safety evaluation is conducted as per the requirements of the standard	The electrical, mechanical and thermal safety evaluation is conducted as per the requirements of the standard

ID	Comparison Item	Proposed Device C32SP+/C32S+	Predicate Device Nio Color 3MP LED
		IEC 60601-1.	IEC 60601-1.
9	Electromagnetic Compatibility		
9.1	EMC Evaluation	Complying with IEC 60601-1-2	Complying with IEC 60601-1-2

8.4 Discussion of Differences:

It is reasonable that there are some differences between our new system and its predicate. All of parameters comply with 21CFR1020.33 and related IEC standards. We did not use any new technology in this system, so those differences between our new system and its predicate do not affect the safety and effectiveness (SE).

Review of ID 1 - Intended use, both of them are intended to be used in displaying and viewing digital images(excluding digital mammography) for review and analysis by trained medical practitioners. So the SE is not affected.

Review of ID 2 - Performance, except the item as below, it is the same, so the SE is not affected.

1. Contrast Ratio, The proposed device is 1400:1 and the predicate device is 1300:1, but the 1400:1 is better than 1300:1 in terms of the image quality. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Review of ID 3 - Physical Specifications, Dimensions and Relative humidity are comparable, so the SE is not affected

Review of ID 4 - Power Supply, both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Review of ID 5 - Human factors, both are the same, so the SE is not affected.

Review of ID 6 - Biocompatibility, both are the same, so the SE is not affected.

Review of ID 7 - Sterility, both are the same, so the SE is not affected.

Review of ID 8 - Electrical & Mechanical safety& Thermal safety, both are the same, so the SE is not affected.

Review of ID 9 - EMC, both are the same, so the SE is not affected.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and

based on the information provided in this premarket notification, Shenzhen Beacon Display Technology Co., Ltd concludes that C32SP+/C32S+ 3MP Color LCD display is substantially equivalent to predicate devices with regard to safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Shenzhen Beacon Display Technology Co., Ltd.
% Ms. Wu Qin
Room 201, Incubator Building, CASTD
High-tech South 1st Street
Shenzhen, Guangdong 518057
CHINA

Re: K140108

Trade/Device Name: 3MP Color LCD Display
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 26, 2013
Received: January 15, 2014

Dear Ms. Qin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140108

Device Name: C32SP+/C32S+ 3MP Color LCD Display

Indications for Use:

The C32SP+/C32S+ 3MP Color LCD Display is intended to be used in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

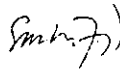
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K140108

Page 1 of ____